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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,500	04/02/2004	Frank Jao	ARC 2258 C1	3152

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,500	JAO ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) and Applicant's Arguments/Remarks, all filed 12/10/07 is acknowledged.

Claims 1 and 4-10 are pending in this action. Claim 11 has been cancelled herein. Claims 2 and 3 have previously been cancelled. Claims 1 and 4-10 are rejected.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/10/07 has been entered.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes *et al.* (U.S. Patent No. 4,058,122) (hereinafter "Theeuwes") in view of Edgren *et al.* (U.S. Pat. No. 5,190,763) (hereinafter "Edgren").

The instant invention is drawn to a dosage form for delivering an antiepileptic drug to a gastrointestinal tract, comprising: a compartment containing a drug formulation layer, the drug formulation layer comprising an antiepileptic drug; a semipermeable wall surrounding the compartment, the semipermeable wall having a passageway that allows communication between the compartment and an exterior of the dosage form; an internal lamina formed on an inner surface of the semipermeable wall, the internal lamina being substantially soluble in water, wherein the internal lamina comprises one or more water-soluble polymers, and he one or more water-soluble polymers are present in the internal lamina in an amount of at least 80% by weight; wherein the internal lamina in a hydrated state forms a gelatinous layer that lubricates the semipermeable wall, thereby substantially preventing crack formation in the semipermeable wall while the dosage form is dispensing the drug.

Theeuwes *et al.* ('122) teach an osmotic system for delivering an agent. The system comprises a wall surrounding a compartment and has a passageway for delivering agent from the compartment. The wall is formed of laminae comprising a lamina consisting of a multiplicity of materials in laminar arrangement with a lamina consisting of a material or of a multiplicity of materials to provide a laminated wall that is permeable to agents and maintains its integrity during delivery of the agent. The compartment contains an agent that is soluble in an external fluid and exhibits an osmotic pressure gradient across the wall against the fluid or the agent has limited solubility in the fluid and is mixed with an osmotically effective compound soluble in the fluid and exhibits an osmotic pressure gradient across the wall against the fluid. Agent is released from the system by fluid being imbibed through the wall into the compartment at a rate controlled by the permeability of the wall and the osmotic pressure gradient across the wall producing a solution-containing agent or a solution of compound-containing agent (see Abstract). The laminated wall is formed of at least one semipermeable lamina; (col. 1, line 14 - col. 3, line 10).

The drawings demonstrate various osmotic systems of the invention. Figs. 1A and 1B, for instance, demonstrate an osmotic system 10 in the form of an oral, osmotic therapeutic system that is comprised of a body 11 having a semipermeable laminated wall 12 that surrounds a compartment 1, seen in Fig. 1B in opened section with a portion of wall 12 removed at 14. System 10 has a passageway 15 in wall 12 that extends through 12 and communicates with compartment 13 and the exterior of system 10. Compartment 13 is a means for containing a beneficial agent 16 that is soluble in an external fluid and exhibits an osmotic pressure gradient across wall 12 against an external fluid or compartment 13 optionally contains a mixture of

agents 16 with at least one agent exhibiting an osmotic pressure gradient (col. 3, line 54 – col. 4, line 14).

In Fig. 1C, wall 12 comprises a lamina consisting of an exterior semipermeable lamina 19 and an interior semipermeable lamina 20.

In one embodiment, lamina 19 is a composite comprising at least two materials blended to form a lamina that is (a) permeable to the passage of an external fluid, (b) maintains its physical and chemical integrity in the environment of use, and is more particularly substantially non-erodible and inert in the environment, c) provides mechanical support for other laminae comprising wall 12 and d) optionally is impermeable to compounds present in the environment of use (col. 4, lines 15-31).

In one embodiment, lamina 20 is a composite comprising at least two materials blended to form a semipermeable lamina that is (e) permeable to the passage of an external fluid, (f) substantially impermeable to passage of the agent and compound present in the compartment, (g) maintains its physical and chemical integrity in the presence of agent and is more particularly substantially non-erodible and inert in the presence of agent, h) provides mechanical support for other laminae forming wall 12 and i) is substantially impermeable to compounds present in the environment of use (col. 4, lines 32-61).

Materials suitable for forming laminae consisting of a single material are generically polymeric materials. The polymeric materials are homopolymers and copolymers and they include materials known as semipermeable, osmosis and reverse osmosis materials (col. 7, line 22 – col. 8, line 6).

Representative materials of the wall include polymeric cellulose esters and copolymeric cellulose esters such as cellulose acylate, cellulose diacylate and cellulose triacylate (mono, di and tricellulose acylates) (col. 8, lines 7-10).

The semipermeable laminae forming materials also include cellulose ethers such as alkylcellulose, methylcellulose, ethylcellulose, ethylmethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose and the like (col. 10, lines 4-19).

Other semipermeable materials useful for forming laminae include copolymers of alkylene oxides and alkyl glycidyl ethers (col. 10, lines 20-47).

Active drugs for use in the invention include drugs that act on the central nervous system such as hypnotics and sedatives, including pentobarbital sodium, phenobarbital, secobarbital, thiopental and mixtures thereof (col. 20, lines 7-12).

It is noted that Theeuwes does not explicitly teach the instantly claimed percentage of water-soluble polymers (of at least 80% by weight). However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance, Applicants have not demonstrated any superior or unexpected results, which accrue from the claimed weight amount of water soluble polymer. The prior art recognizes and teaches a structurally similar dosage formulation comprising similar ingredients, used for the same field of endeavor as that of the Applicants.

In any event, the **Edgren ('763)** reference is relied upon for the teaching of the use of high amounts of water-soluble polymers, such as polvinylpyrrolidone, used in amounts of 0 wt. % to 75 wt %, formulated in an osmotic dosage device (see col. 5, lines 45-54). Edgren teaches that their osmotic dosage device comprises a wall (12) that surrounds and defines an internal compartment (15). The wall (12) comprises at least one exit means (13) that connects compartment (15) with the exterior of dosage form (10). Dosage form (10) can comprise more than one exit means. Representative materials for the semipermable wall include cellulose acylate, cellulose diacylate, cellulose triacylate (see col. 3, line 42 – col. 4, line 17). Water-soluble polymers are disclosed at for example column 5, lines 45-65.

It would have been obvious to one of ordinary skill in the art to incorporate high amounts of water-soluble polymers as taught by Edgren within the dosage devices of Theeuwes. One of ordinary skill in the art would do so with a reasonable expectation of success because Edgren teaches a dosage device comprising an internal compartment that comprises a composition made of high amounts of polymer, such as 75 wt % polyvinylpyrrolidone and suggests that such high amounts are beneficial for their drug delivery dosage form. The expected result would be an effective dosage delivery system for the treatment of disorders and diseases.

It is the position of the Examiner that no patentable distinction has been observed, which accrues from the "at least 80% by weight of polymers" claimed. The prior art teaches the use of high levels of water-soluble polymers and teaches the benefits obtained there from. The difference is a difference solely in degree and not of kind.

Hence, given the teachings of Theeuwes in view of Edgren discussed above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Pertinent Art

Prior Art made of record, not relied upon and cited of interest:

Khan *et al.* (U.S. Pat. No. 5,656,296) (08/1997):

Khan *et al.* teach dual control sustained release drug delivery systems and methods for preparing, whereby the system comprises a core and a porous coating layer over the core (Abstract). Suitable drugs taught include antiepileptics, such as sodium phenytoin (col. 3, line 44). The water-soluble film-forming polymer is present in an amount from about 20% to about 60% (col. 2, lines 35-36).

Response to Arguments

Applicant's arguments filed 12/10/07 have been fully considered but were not found persuasive.

Rejection under 35 U.S.C. §103(a) over Theeuwes et al. (US 4,058,122):

Applicant argued, "The superior result that accrues from the claimed percentage of water soluble polymer in claims 1 and 4-10 is that the internal lamina dissolves and forms a gelatinous layer which lubricates the semipermeable wall and substantially prevents the semipermeable wall from cracking while the dosage form is dispensing the drug. This is not disclosed or suggested by Theewes et al. Theeuwes et al teach an internal semipermeable lamina that maintains its physical and chemical integrity while the dosage is dispensing the drug".

Applicant's arguments have been considered, but were not deemed persuasive. The Theeuwes reference discloses the use of polymers that are water-soluble. The percentage of water-soluble polymers claimed by Applicant of "at least 80% by weight", while not disclosed by Theeuwes, does not provide for a "patentable" distinction over the osmotic structures of the cited reference, because the difference is a difference in degree and not of kind. The issue here is whether the prior art teaches and/or suggests the advantage and benefits of the use of such water-soluble polymers in a dosage form such as that claimed by Applicant, which in this case, it clearly does. The prior art teaches the inclusion of the same ingredients (i.e., antiepileptic), being used in the same art area to achieve similar results as instantly claimed. The issue of the benefits of the use of water-soluble polymers is vividly suggested in the art. The determination of the precise amounts of (water-soluble) polymers can be carried out through manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Applicant has the burden of establishing by a showing of scientific data, the reduced effectiveness alleged in the response of the lower amounts of water-soluble polymers, as disclosed in the art. Furthermore, it should be noted that the claim limitation of "the internal lamina in a hydrated state" denotes a future-intended use limitation, which does not accord patentable weight to the claims. Thus, Applicant's assertion of superior results does not patentably define and distinguish over the explicit teachings of Theeuwes. The prior art, as delineated above, is drawn to a similar formulation having essentially similar components, for use in the same field of endeavor as the Applicants.

Thus, Applicant's arguments were not found persuasive.

Conclusion

-- No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

February 18, 2008